K100669

APR - 6 2011

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information:

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Attn: Jerome Canady, M.D.

Date Summary Prepared: July 27, 2010

Application Correspondent:

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Senior Regulatory Consultant
Emergo Group Inc.
611 West 5th Street
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Austin, Texas 78701
Tel: 512-327-9997
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Device Name:

Trade Name(s): Canady Plasma™ Electrosurgical Unit Series (SS-601 MCa, SS-200E)/
Canady Plasma™ Coagulator (Argon 2 and 4) with Accessories
Canady Plasma™ Probes for Flexible Endoscopy

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Regulation: 21 CFR 878.4400
Panel: General, Restorative, and Neurological Devices
Product Code: GEI
Class: II

Predicate Device Information:

Canady Technology, LLC Canady Plasma Probes for Flexible Endoscopy – K052035
ERBE ICC 200 – K933157
ERBE VIO 300D – K023886
ERBE VIO APC2 – K024047
ERBE APC Applications – K013348
Valley Lab Force FX – K944602
BOVIE IDS-300 K022856

Device Description:
The Canady Plasma™ Electrosurgical Unit Series with Accessories is an High Frequency (HF) Electrosurgery Unit (ESU) used in combination with Canady Plasma™ Coagulators (Argon 2 and Argon 4) gas units and probes (Canady Plasma™ GIT probe and Canady Plasma™ TBS probe). The Canady Plasma (ESU) series combines (HF) voltage to electrically enhanced plasma gas (i.e. Argon) to produce a plasma gas stream. Current density upon arrival at the tissue surface from Canady Plasma Probes causes coagulation of the tissue. Canady Plasma (ESU) series is also a monopolar and bipolar RF surgical device for cutting and coagulation. It is used for tissue removal and coagulation in accordance with the operative procedure performed by the physician. The unit provides various cutting and coagulation modes to meet the physician flexibility performing the specific procedure with the device.

The Canady Plasma Electrosurgery Unit Model SS-200E is to only be used with the Canady Plasma Coagulator Argon 2. The Canady Plasma Electrosurgery Unit Model SS-601Mca is to only be used with the Canady Plasma Coagulator Argon 4.

Intended Use:
The Canady Plasma Coagulator devices are intended to provide gas-enhanced coagulation during general surgery procedures. The Canady Plasma Coagulator devices are Argon Plasma Coagulation Unit designed for gas enhanced coagulation when used only with the Canady Plasma Electrosurgery Unit models and compatible monopolar and/or bipolar RF handpieces.

The Canady Electrosurgery Unit Generators are intended to cut and/or coagulate tissue when used with compatible monopolar and/or bipolar RF handpieces. The Canady Electrosurgery Unit Generators are capable of monopolar argon gas enhanced coagulation when used with Canady Plasma Coagulator and probes.

Comparison to Predicate Devices:
These devices are equivalent in intended use, technological characteristics, and performance characteristics to the named predicate devices.

Testing and Conclusions:
The devices comply with NBR IEC 60601-1 Standard, Electromedical equipment – Part 1 – General requirements for safety, NBR IEC 60601 – 2- 2 Electromedical equipment - Part 2 – 2: Particular requirements for the safety of high frequency surgical equipment, NBR IEC 60601 – 1 – 2, Electromedical equipment – Part 1 – 2: Collateral standard: Electromagnetic compatibility – Requirements and test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

US Medical Innovations LLC
% TUV SUD America, Inc.
Ms. Dawn Tibodeau
1775 Old Highway 8 NW, Ste 104
New Brighton, Minnesota 55112-1891

APR - 6 2011

Re: K100669
Trade/Device Name: Canady Plasma Electrosurgical Unit Series & Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 29, 2011
Received: April 6, 2011

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K100669

Device Name: Canady Plasma™ Electrosurgical Unit Series with Accessory Probes

Indications for Use:

The Canady Plasma Coagulator devices are intended to provide gas-enhanced coagulation during general surgery procedures. The Canady Plasma Coagulator devices are Argon Plasma Coagulation Unit designed for gas enhanced coagulation when used only with the Canady Plasma Electrosurgery Unit models and compatible monopolar and/or bipolar RF handpieces.

The Canady Electrosurgery Unit Generators are intended to cut and/or coagulate tissue when used with compatible monopolar and/or bipolar RF handpieces. The Canady Electrosurgery Unit Generators are capable of monopolar argon gas enhanced coagulation when used with Canady Plasma Coagulator and probes.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100669